Cardiovascular Systems Inc
Form 10-K
September 28, 2010

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended June 30, 2010

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 000-52082

CARDIOVASCULAR SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**41-1698056**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
651 Campus Drive **St. Paul, Minnesota** *(Address of principal executive offices)*	**55112-3495** *(Zip Code)*

Registrant s telephone number, including area code:
(651) 259-1600

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, One-tenth of One Cent ($0.001) Par Value Per Share	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act:
None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller reporting company þ
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

As of December 31, 2009, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was $49,227,511 based on the closing sale price as reported on the NASDAQ Global Market.

The number of shares of the registrant s common stock outstanding as of September 23, 2010 was 15,694,291.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the registrant s 2010 Annual Meeting of Stockholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this report.

Table of Contents

We make available, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act on our web site, *http://www.csi360.com*, as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. We are not including the information on our web site as a part of, or incorporating it by reference into, our Form 10-K.

Table of Contents

PART I

Item 1. *Business.*

Special Note Regarding Forward Looking Statements

This report contains plans, intentions, objectives, estimates and expectations that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plans, anticipates, believes, estimates, pr potential and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, any statements regarding our future financial performance, results of operations or sufficiency of capital resources to fund our operating requirements, and other statements that are other than statements of historical fact. Our actual results could differ materially from those discussed in these forward-looking statements due to a number of factors, including the risks and uncertainties are described more fully by us in Part I, Item 1A and Part II, Item 7 of this report and in our other filings with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this report. You should read this report completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Corporate Information

We were incorporated as Replidyne, Inc. in Delaware in 2000. On February 25, 2009, Replidyne, Inc. completed its business combination with Cardiovascular Systems, Inc., a Minnesota corporation (CSI-MN), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of November 3, 2008, by and among Replidyne, Responder Merger Sub, Inc., a wholly-owned subsidiary of Replidyne (Merger Sub), and CSI-MN (the Merger Agreement). Pursuant to the Merger Agreement, Merger Sub merged with and into CSI-MN, with CSI-MN continuing after the merger as the surviving corporation and a wholly-owned subsidiary of Replidyne. At the effective time of the merger, Replidyne changed its name to Cardiovascular Systems, Inc. (CSI) and CSI-MN changed its name to CSI Minnesota, Inc. As of immediately following the effective time of the merger, former CSI-MN stockholders owned approximately 80.2% of the outstanding common stock of the combined company, and Replidyne stockholders owned approximately 19.8% of the outstanding common stock of the combined company. Following the merger of Merger Sub with CSI-MN, CSI-MN merged with and into CSI, with CSI continuing after the merger as the surviving corporation. These transactions are referred to herein as the merger. Unless the context otherwise requires, all references herein to the Company, CSI, we, us and our refer to CSI-MN prior to the completion of the merger an CSI following the completion of the merger and the name change, and all references to Replidyne refer to Replidyne prior to the completion of the merger and the name change.

Replidyne was a biopharmaceutical company focused on discovering, developing, in-licensing and commercializing anti-infective products.

CSI-MN was incorporated in Minnesota in 1989. From 1989 to 1997, we engaged in research and development on several different product concepts that were later abandoned. Since 1997, we have devoted substantially all of our

resources to the development of the Diamondback Systems and our Viper line of ancillary products.

Our principal executive office is located at 651 Campus Drive, St. Paul, Minnesota 55112. Our telephone number is (651) 259-2800, and our website is www.csi360.com. The information contained in or connected to our website is not incorporated by reference into, and should not be considered part of, this Annual Report on Form 10-K.

Table of Contents

We have received federal registration of certain marks including Diamondback 360° , CSI , CSI logo, Lumen Library ViperWire , ViperWire Advance , ViperSlide , and ViperTrack. We have applied for federal registration of certain marks, including ViperCaddy , Predator 360° , and Stealth 360°. All other trademarks, trade names and service marks appearing in this Form 10-K are the property of their respective owners.

Business Overview

We are a medical device company focused on developing and commercializing minimally invasive treatment solutions for vascular disease. Interventional endovascular treatment of peripheral artery disease, or PAD, was our initial area of focus. PAD is caused by the accumulation of plaque in peripheral arteries, most commonly occurring in the pelvis and legs. PAD is a progressive disease, and, if left untreated, can lead to limb amputation or death.

Our primary products, the Diamondback 360°® PAD System (Diamondback 360°) and the Diamondback Predator 360°™ PAD System (Predator 360°), are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee and address many of the limitations associated with existing treatment alternatives. We refer to the Diamondback 360° and the Predator 360° collectively in this report as the Diamondback Systems. We commenced a limited commercial introduction of the Diamondback 360° in the United States in September 2007 and began a full commercial launch during the quarter ended March 31, 2008. We commenced commercial launch of the Predator 360° in April 2009. As of June 30, 2010, the Diamondback Systems have been utilized in an estimated 29,000 procedures. We intend to leverage the capabilities of the Diamondback Systems to expand into the interventional coronary market.

In addition to the Diamondback Systems, we are expanding our product portfolio through internal product development and establishment of business relationships. We now offer multiple accessory products designed to complement the use of the Diamondback Systems, and we have entered into distribution agreements with Medtronic, Inc. and Asahi-Intecc, Ltd.

Market Overview

PAD is a circulatory problem in which plaque deposits build up on the walls of arteries, reducing blood flow to the limbs. The most common early symptoms of PAD are pain, cramping or fatigue in the leg or hip muscles while walking. Symptoms may progress to include numbness, tingling or weakness in the leg and, in severe cases, burning or aching pain in the leg, foot or toes while resting. As PAD progresses, additional signs and symptoms occur, including cooling or color changes in the skin of the legs or feet, and sores on the legs or feet that do not heal. If untreated, PAD may lead to critical limb ischemia, a condition in which the amount of oxygenated blood being delivered to the limb is insufficient to keep the tissue alive. Critical limb ischemia often leads to large non-healing ulcers, infections, gangrene and, eventually, limb amputation or death.

PAD affects approximately eight to 12 million people in the United States, as cited by the authors of the PARTNERS study published in the Journal of the American Medical Association in 2001. According to 2007 statistics from the American Heart Association, PAD becomes more common with age and affects approximately 12% to 20% of the population over 65 years old. An aging population, coupled with increasing incidence of diabetes and obesity, is likely to increase the prevalence of PAD. In many older PAD patients, particularly those with diabetes, PAD is characterized by fibrotic (moderate) or calcified (hardened) plaque deposits that have not been successfully treated with existing non-invasive treatment techniques. PAD may involve arteries either above or below the knee. Arteries above the knee are generally long, straight and relatively wide, while arteries below the knee are shorter and branch into arteries that are progressively smaller in diameter.

Despite the severity of PAD, it remains relatively underdiagnosed. According to an article published in Podiatry Today in 2006, only approximately 2.5 million of the eight to 12 million people in the United States with PAD are diagnosed. Although we believe the rate of diagnosis of PAD is increasing, underdiagnosis continues due to patients failing to display symptoms or physicians misinterpreting symptoms as normal aging. Recent emphasis on PAD education from medical associations, insurance companies and other groups, coupled with publications in medical journals, is increasing physician and patient awareness of PAD risk factors, symptoms and treatment options. The PARTNERS study advocated increased PAD screening by primary care physicians.

Table of Contents

Physicians treat a significant portion of the 2.5 million people in the United States who are diagnosed with PAD using medical management, which includes lifestyle changes, such as diet and exercise and drug treatment. For instance, within a reference group of over 1,000 patients from the PARTNERS study, 54% of the patients with a prior diagnosis of PAD were receiving antiplatelet medication treatment. While medications, diet and exercise may improve blood flow, they do not treat the underlying obstruction and many patients have difficulty maintaining lifestyle changes. Additionally, many prescribed medications are contraindicated, or inadvisable, for patients with heart disease, which often exists in PAD patients. As a result of these challenges, many medically managed patients develop more severe symptoms that require procedural intervention.

Our Solution

The Diamondback Systems represent a new approach to the treatment of PAD that provides physicians and patients with a procedure that addresses many of the limitations of traditional treatment alternatives. The Diamondback Systems each use single-use catheters that incorporate a flexible drive shaft with an offset diamond grit coated crown. Physicians position the crown at the site of an arterial plaque-containing lesion and remove the plaque by causing the crown to orbit against it, creating a smooth lumen, or channel, in the vessel. The Diamondback Systems are designed to differentiate between hard plaque and soft, compliant arterial tissue, a concept that we refer to as differential sanding.

Normal arteries are compliant; they have the ability to expand and contract as needed to supply blood flow to the legs and feet. Arteries burdened with fibrotic (moderately hard) and/or calcified (extremely hard) plaque due to PAD lose their compliance which makes other therapies such as angioplasty, stenting, surgical bypass and atherectomy problematic. The Diamondback Systems sand plaque into small particles and restore both blood flow and vessel compliance. The particles created by the Diamondback Systems are generally smaller than red blood cells and are carried away by the bloodstream. The small size of the particles avoids the need for plaque collection reservoirs. The Diamondback Systems can typically treat the diseased arteries with less than two to three minutes of sanding time, potentially reducing the overall procedure time.

We believe that the Diamondback Systems offer the following key benefits:

Strong Safety Profile

Differential Sanding Reduces Risk of Adverse Events. The Diamondback Systems are designed to differentiate between hard plaque and soft compliant arterial tissue. Arteries are composed of three tissue layers. The diamond grit coated offset crown at the working end of the devices engages and removes plaque from the artery wall with minimal likelihood of penetrating or damaging the fragile, inner layer of the arterial wall because soft, compliant tissue flexes away from the crown. Furthermore, the Diamondback Systems have rarely penetrated even the middle or outer layers of the artery s wall. The Diamondback 360° s perforation rate was 2.4% during our pivotal OASIS trial. Analysis by an independent pathology laboratory of more than 434 consecutive cross sections of porcine arteries treated with the Diamondback 360° revealed there was minimal to no damage, on average, to the middle layer, which is typically associated with restenosis. In addition, the safety profile of the Diamondback 360° was found to be non-inferior to that of angioplasty, which is often considered the safest of interventional methods. This was demonstrated in our OASIS trial, which had a low 4.8% rate of device-related serious adverse events, or SAEs.

Reduces the Risk of Distal Embolization. The Diamondback Systems sand plaque away from artery walls in a manner that produces particles of such a small size generally smaller than red blood cells that they are carried away by the bloodstream. The small size of the particles avoids the need for plaque collection reservoirs on the catheter and reduces the need for ancillary distal protection devices, commonly used with directional cutting

atherectomy, and also significantly reduces the risk that larger pieces of removed plaque will block blood flow downstream.

Allows Continuous Blood Flow During Procedure. The Diamondback Systems allow for continuous blood flow during the procedure, except when used in chronic total occlusions. Other devices may restrict blood flow due to the size of the catheter required or the use of distal protection devices, which could result in complications such as excessive heat and tissue damage.

Table of Contents

Proven Efficacy

Efficacy Demonstrated in a 124-Patient Clinical Trial. Our pivotal OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions treated by the Diamondback 360°. Performance targets were established cooperatively with the FDA before the trial began. Despite 55% of the lesions consisting of calcified plaque and 48% of the lesions having a length greater than three centimeters, the performance of the Diamondback 360° in the OASIS trial successfully met the FDA s study endpoints. Because the Predator 360° mechanism of action is identical to that of the Diamondback 360°, no additional efficacy trials were required by the FDA for 510(k) clearance of the Predator 360°.

Treats Difficult, Fibrotic and Calcified Lesions. The Diamondback Systems enable physicians to remove plaque from long, fibrotic, calcified or bifurcated lesions in peripheral arteries both above and below the knee. Other PAD devices have demonstrated limited effectiveness in treating these challenging lesions.

Orbital Motion Improves Device-to-Lumen Ratio. The orbiting action of the Diamondback Systems can create a lumen of approximately 2.0 times the diameter of the crown. The variable device-to-lumen ratio allows the continuous removal of plaque as the opening of the lumen increases during the operation of the devices. Non-orbiting rotational atherectomy catheters remove plaque by abrading the lesion with a spinning, abrasive burr, which acts in a manner similar to a drill and only creates a lumen the same size or slightly smaller than the size of the burr.

Differential Sanding Creates Smooth Lumens. The differential sanding of the Diamondback Systems creates a smooth surface inside the lumen. We believe that the smooth lumens created by the devices increase the velocity of blood flow and decrease the resistance to blood flow which may decrease potential for restenosis, or renarrowing of the arteries.

Ease of Use

Utilizes Familiar Techniques. Physicians using the Diamondback Systems employ techniques similar to those used in angioplasty, which are familiar to interventional cardiologists, vascular surgeons and interventional radiologists who are trained in endovascular techniques. The devices simple user interfaces require minimal additional training. The devices ability to differentiate between diseased and compliant tissue reduces the risk of complications associated with user error and potentially broadens the user population.

Single Insertion to Complete Treatment. The orbital technology and differential sanding process of the Diamondback Systems allows for a single insertion to treat lesions, in most cases. Because the particles of plaque sanded away are of such small sizes, the Diamondback Systems do not require a collection reservoir that needs to be repeatedly emptied or cleaned during the procedure. Rather, the Diamondback Systems allow for multiple passes of the device over the lesion until plaque is removed and a smooth lumen is created.

Limited Use of Fluoroscopy. The relative simplicity of our process and predictable crown location allows physicians to significantly reduce fluoroscopy use, thus limiting radiation exposure.

Cost and Time Efficient Procedure

Short Procedure Time. The Diamondback Systems have a short treatment time. Treatment with the Diamondback 360° typically ranges from three to six minutes, while treatment time with the Predator 360° is typically shorter ranging from 90 seconds to three minutes.

Single Crown Can Create Various Lumen Sizes Limiting Hospital Inventory Costs. The orbital mechanism of action with the Diamondback Systems allows a single-sized device to create various diameter lumens inside the artery. Adjusting the rotational speed of the crown changes the orbit to create the desired lumen diameter, thereby potentially avoiding the need to use multiple catheters of different sizes to treat multiple lesions. The Diamondback Systems can create a lumen that is 100% larger than the actual diameter of the device, for a device-to-lumen ratio of approximately 1.0 to 2.0.

Table of Contents

Single Insertion Reduces Procedural Time. Since the physician does not need to insert and remove multiple catheters or clean a plaque collection reservoir to complete the procedure, there is a potential for decreased procedure time.

Our Strategy

Our goal is to be the leading provider of minimally invasive solutions for the treatment of vascular disease. The key elements of our strategy include:

Drive Adoption Through Our Direct Sales Organization and Key Physician Leaders. We expect to continue to drive adoption of the Diamondback Systems through our direct sales force, which targets interventional cardiologists, vascular surgeons and interventional radiologists. As a key element of our strategy, we focus on educating and training physicians on the Diamondback Systems through our direct sales force and during seminars where physician industry leaders discuss case studies and treatment techniques using the devices.

Collect Additional Clinical Evidence on Benefits of the Diamondback Systems. Physicians are increasingly requesting clinical study evidence to allow them to make the best treatment decisions to achieve the best possible short-term and long-term outcomes for their patients. We are focused on collecting and using clinical evidence to demonstrate the advantages of the Diamondback Systems and drive physician acceptance. We have conducted four clinical trials to demonstrate the safety and efficacy of the Diamondback 360° in treating PAD, involving 935 patients, including PAD I and PAD II pilot trials, our pivotal OASIS trial and our CONFIRM DIAMONDBACK Registry. In addition, we have completed enrollment in two clinically rigorous, randomized post-market feasibility trials to further differentiate the performance of the Diamondback 360° from conventional balloon angioplasty. In both of these studies, the CALCIUM 360° and COMPLIANCE 360°, acute procedural success and device safety will be verified by an independent core lab, and the long-term durability of the procedure will be evaluated. Finally, we are currently enrolling up to 1,200 patients in the CONFIRM PREDATOR Registry. In this registry, we will collect acute clinical data to further demonstrate the ability of the Predator 360° to rapidly and effectively treat lesions above and below the knee.

Expand Product Portfolio within the Market for Treatment of Peripheral Arteries. In addition to the Diamondback Systems, we are expanding our product portfolio. We now offer multiple accessory devices designed to complement the use of the Diamondback Systems. We continue to market the following products:

ViperSlide® Lubricant an exclusive lubricant designed to optimize the smooth operation of the Diamondback Systems

ViperTrack® Radiopaque Tape a radiopaque tape to assist in measuring lesion lengths and marking lesion locations

We are continuing to actively pursue internal product development to further expand our portfolio of PAD treatment solutions.

Leverage Technology Platform into Coronary Market. Based on the excellent clinical performance of the Diamondback Systems in treating lower extremity PAD, we intend to leverage the devices capabilities to expand into the interventional coronary market. A coronary application would address a large market opportunity, further leveraging our core technology and expanding its market potential. In 2008, we completed the ORBIT I trial, a 50-patient study in India that investigated the safety of the Diamondback 360º device in treating calcified coronary artery lesions. Results successfully met both safety and efficacy endpoints. An

investigational device exemption, or IDE, application has been approved by the FDA for ORBIT II, a pivotal 429 patient trial in the United States to evaluate the safety and effectiveness of the Diamondback 360º in treating severely calcified coronary lesions. Patient enrollment in ORBIT II is currently underway.

Table of Contents

Pursue Strategic Acquisitions and Partnerships. We have ongoing agreements with both Medtronic, Inc. and Asahi-Intecc, Ltd. In April 2009, we signed a sales agency agreement with Invatec, Inc. to distribute the Invatec balloon catheter line, including the SubMarine Plus™ PTA Balloon Catheter, the Admiral Xtreme™ PTA Balloon Catheter and the Amphirion Deep™ PTA Balloon Catheter. These balloons are typically used at low pressure, if needed, following the restoration of vessel compliance with the Diamondback Systems. Medtronic, Inc. recently acquired Invatec, Inc, and we continue to market these balloons under a new agreement with Medtronic, Inc. that expires on September 30, 2010 unless renewed. In August 2009, we signed an exclusive distribution agreement with Asahi-Intecc, Ltd. to market its peripheral guide wire line in the United States. We offer two Asahi 0.18 wire platforms: the Astato 30 and Treasure 12. The Astato 30 is a high-penetration guide wire specially designed to break through fibrous caps and calcium deposits, and treat long, complex lesions. The Treasure 12 has a one-piece core to provide control, torque performance and tactile feedback to the physician.

In addition to adding to our product portfolio through internal development efforts, we intend to continue to explore the acquisition of other product lines, technologies or companies that may leverage our sales force or complement our strategic objectives. We plan to continue to evaluate distribution agreements, licensing transactions, other strategic partnerships, and the financial viability of marketing the Diamondback Systems internationally.

Our Product

Components of the Diamondback Systems

The Diamondback Systems each use a single-use, low-profile catheter that travels over our proprietary ViperWire Advance™ Guide Wire. The system is used in conjunction with a reusable external control unit.

Catheter. The catheter consists of:

a control handle, which allows precise movement of the crown and predictable crown location;

a flexible drive shaft with a diamond grit coated offset crown, which tracks and orbits over the guidewire; and

a sheath, which covers the drive shaft and permits delivery of saline or medications to the treatment area.

ViperWire Advance Guidewire. The ViperWire Advance is the second generation of the ViperWire. The ViperWire Advance was designed to offer an improved ability to maneuver through tortuous, twisting blood vessels and cross challenging lesions. The Diamondback Systems travel over this wire to the lesion and operate on this wire. The ViperWire is available in two levels of firmness.

Control Unit. The control unit incorporates a touch-screen interface on an easily maneuverable, lightweight pole. Using an external air supply, the control unit regulates air pressure to drive the turbine located in the catheter handle to speeds ranging up to 200,000 revolutions per minute. Saline, delivered by a pumping mechanism on the control unit, bathes the device shaft and crown. The constant flow of saline reduces the risk of heat generation.

Technology Overview

The two technologies used in the Diamondback Systems are plaque modification through differential sanding and plaque removal.

Plaque Modification through Differential Sanding. The Diamondback Systems were designed to allow the devices to differentiate between soft compliant and harder diseased arterial tissue. This property is consistent with sanding material such as the diamond grit used in the Diamondback Systems. The diamond preferentially engages and sands harder material. The Diamondback Systems also treat soft plaque, which is still harder than a normal vessel wall. Arterial lesions tend to be harder and stiffer than compliant, undiseased tissue, and they often are fibrotic or calcified. The Diamondback Systems sand the lesion but are designed not to damage more compliant parts of the artery. The mechanism is a function of the centrifugal force generated by the Diamondback Systems as they rotate. As the crown moves outward, the centrifugal force is offset by the counterforce exerted by the arterial

Table of Contents

wall. If the tissue is compliant, it flexes away, rather than generating an opposing force that would allow the Diamondback Systems to engage and sand the wall. Diseased tissue provides resistance and is able to generate an opposing force that allows the Diamondback Systems to engage and sand the plaque. The sanded plaque is broken down into particles generally smaller than circulating red blood cells that are washed away downstream with the patient s natural blood flow. Of 36 consecutive experiments that we performed in carbon blocks, animal and cadaver models:

93.1% of particles were smaller than a red blood cell, with a 99% confidence interval; and

99.3% of particles were smaller than the lumen of the capillaries (which provide the connection between the arterial and venous system), with a 99% confidence interval.

The small particle size minimizes the risk of vascular bed overload, or a saturation of the peripheral vessels with large particles, which may cause slow or reduced blood flow to the foot. We believe that the small size of the particles also allows them to be managed by the body s natural cleansing of the blood, whereby various types of white blood cells eliminate worn-out cells and other debris in the bloodstream.

Plaque Removal. The systems operate on the principles of centrifugal force. As the speed of the crown s rotation increases, it creates centrifugal force, which increases the crown s orbit and presses the diamond grit coated offset crown against the lesion or plaque, removing a small amount of plaque with each orbit. The characteristics of the orbit and the resulting lumen size can be adjusted by modifying three variables:

Speed. An increase in speed creates a larger lumen. Our current systems allow the user to choose between three rotational speeds.

Crown Characteristics. The crown can be designed with various weights (as determined by different materials and density) and coated with diamond grit of various width, height and configurations. The Diamondback 360° crown is available in two configurations classic and solid. The classic crown addresses treatment needs in arteries typically below the knee and in more tortuous anatomy, while the solid crown addresses treatment needs in larger arteries typically above the knee. The Predator 360° crown is available in the solid configuration and is constructed to allow the crown to engage and treat the lesion more rapidly when shorter procedure times are desired. Both the Diamondback 360° and Predator 360° crowns are available in multiple sizes, including 1.25, 1.50, 1.75, 2.00 and 2.25 millimeter diameters. For both devices, the catheter length is 135 centimeters, which addresses procedural approach and target lesion locations both above and below the knee.

Drive Shaft Characteristics. The drive shaft can be designed with various shapes and degrees of rigidity. We are developing a new drive shaft that may enhance the ability to advance the device more smoothly and effectively through tortuous anatomy and challenging lesion morphologies and potentially enhance the devices performance.

We view the Diamondback Systems as platforms that can be used to develop additional products by adjusting one or more of the speed, crown and shaft variables.

Applications

The Diamondback Systems can be used to treat plaque in multiple anatomic locations.

Below-the-Knee Peripheral Artery Disease. Arteries below the knee have small diameters and may be diffusely diseased, calcified or both, limiting the effectiveness of traditional devices. The Diamondback Systems are effective in both diffuse and calcified vessels. This was demonstrated in the OASIS trial, where 94.5% of lesions treated with the Diamondback 360° were behind or below the knee.

Above-the-Knee Peripheral Artery Disease. Plaque in arteries above the knee may also be diffuse, fibrotic and calcific; however, these arteries are longer, straighter and wider than below-the-knee vessels. While effective in difficult-to-treat below-the-knee vessels, and indicated for vessels up to four millimeters in diameter, our products are also being used to treat lesions above the knee. The Millennium Research Group estimates that there will be

Table of Contents

approximately 258,600 endovascular procedures to treat above-the-knee PAD in 2011 and that there will be approximately 71,220 endovascular procedures to treat below-the-knee PAD in 2011.

Coronary Artery Disease. Given the many similarities between peripheral and coronary artery disease, we have developed a modified version of the Diamondback 360° to treat coronary arteries. We have conducted numerous bench studies, four pre-clinical animal studies, and our ORBIT I 50-patient human clinical study to evaluate the Diamondback 360° in coronary artery disease. In the bench studies, we evaluated the system for conformity to specifications and patient safety, and, under conditions of expected clinical use, no safety issues were observed. In three of the animal studies, the system was used to treat a large number of stented and non-stented arterial lesions. The system was able to safely debulk lesions without evidence or observations of significant distal embolization, and the treated vessels in the animal studies showed only minimal to no damage. The fourth animal study evaluated the safety of the system for the treatment of coronary stenosis. There were no device-related adverse events associated with system treatment during this study, with some evidence of injury observed in 17% of the tissue sections analyzed, although 75% of these injuries were minimal or mild. A coronary application would require us to conduct a clinical trial and receive PMA from the FDA. We participated in three pre-IDE meetings with the FDA and completed the human feasibility portion of a coronary trial in the summer of 2008 in India, enrolling 50 patients. The FDA agreed to accept the data from the India trial to support an IDE submission. The FDA granted unconditional approval in April 2010 to begin the ORBIT II coronary study in the United States. The pivotal trial will initially enroll up to 100 patients at as many as 50 U.S. sites, with the potential to enroll up to 429 patients.

Clinical Trials and Studies for Our Products

CSI is committed to providing relevant clinical evidence to allow physicians to select and utilize the best treatment options for their patients. We have conducted four clinical trials to demonstrate the safety and efficacy of the Diamondback 360° in treating PAD, enrolling a total of 935 patients in our PAD I and PAD II pilot trials, our pivotal OASIS trial, and our recently completed CONFIRM DIAMONDBACK Post-Market Registry. We have completed a retrospective study evaluating the long-term results of 64 patients from the OASIS Trial in order to determine durability of procedure results. In addition, we have also completed enrollment in two post-market, randomized feasibility studies to further differentiate the performance of the Diamondback 360° from conventional balloon angioplasty. Last, we are currently enrolling up to 1,200 patients in our CONFIRM PREDATOR Post-Market Registry.

The common metrics used to evaluate the efficacy of plaque modification and removal devices for PAD include:

Metric	Description
Absolute Plaque Reduction	Absolute plaque reduction is the difference between the pre-treatment percent stenosis, or the narrowing of the vessel, and the post-treatment percent stenosis as measured angiographically.
Target Lesion Revascularization	Target lesion revascularization rate, or TLR rate, is the percentage of patients at follow-up who have another peripheral intervention precipitated by their worsening symptoms, such as an angioplasty, stenting or surgery to reopen the treated lesion site.
Ankle Brachial Index	The Ankle Brachial Index, or ABI, is a measurement that is useful to evaluate the adequacy of circulation in the legs and improvement or worsening of leg circulation over time. The ABI is a ratio between the blood pressure in a patient s ankle and a patient s arm, with a ratio above 0.9 being normal.

Table of Contents

The common metrics used to evaluate the safety of atherectomy devices for PAD include:

Metric	Description
Serious Adverse Events	Serious adverse events, or SAEs, include any experience that is fatal or life-threatening, is permanently disabling, requires or prolongs hospitalization, or requires intervention to prevent permanent impairment or damage. SAEs may or may not be related to the device.
Perforations	Perforations occur when the artery is punctured during atherectomy treatment. Perforations may be nonserious or an SAE depending on the treatment required to repair the perforation.

Inclusion criteria for trials often limit size of lesion and severity of disease, as measured by the Rutherford Class, which utilizes a scale of I to VI, with I being mild and VI being most severe, and the Ankle Brachial Index.

PAD I Feasibility Trial

Our first trial was a two-site, 17-patient feasibility clinical trial in Europe, which we refer to as PAD I, that began in March 2005. Patients enrolled in the trial had lesions that were less than 10 cm in length in arteries between 1.5 mm and 6.0 mm in diameter, with Rutherford Class scores of IV or lower. Patients were evaluated at the time of the procedure and at 30 days following treatment. The purpose of PAD I was to obtain the first human clinical experience and evaluate the safety of the Diamondback 360°. This was determined by estimating the cumulative incidence of patients experiencing one or more SAEs within 30 days post-treatment.

The results of PAD I were presented at the Transcatheter Therapeutics conference, or TCT, in 2005 and published in American Journal of Cardiology. Results confirmed that the Diamondback 360° was safe and established that the Diamondback 360° could be used to treat vessels in the range of 1.5 mm to 4.0 mm, which are found primarily below the knee. PAD I also showed that removal of plaque could be accomplished and the resulting device-to-lumen ratio was approximately 1.0 to 2.0. The SAE rate in PAD I was 6% (one of 17 patients).

PAD II Feasibility Trial

After being granted the CE Mark in May 2005, we began a 66-patient European clinical trial at seven sites, which we refer to as PAD II, in August 2005. All patients had stenosis in vessels below the femoral artery of between 1.5 mm and 4.0 mm in diameter, with at least 50% blockage. The primary objectives of this study were to evaluate the acute (30 days or less) risk of experiencing an SAE post procedure and provide evidence of device effectiveness. Effectiveness was confirmed angiographically and based on the percentage of absolute plaque reduction.

The PAD II results demonstrated safe and effective debulking in vessels with diameters ranging from 1.5 mm to 4.0 mm with a mean absolute plaque reduction of 55%. The SAE rate in PAD II was 9% (six of 66 patients), which did not differ significantly from existing non-invasive treatment options.

OASIS Pivotal Trial

We received an IDE to begin our pivotal United States trial, OASIS, in September 2005. OASIS was a 124-patient, 20-center, prospective trial that began enrollment in January 2006.

Patients included in the trial had:

- an ABI of less than 0.9;
- a Rutherford Class score of V or lower; and
- treated arteries of between 1.5 mm and 4.0 mm or less in diameter via angiogram measurement, with a well-defined lesion of at least 50% diameter stenosis and lesions of no greater than 10.0 cm in length.

The primary efficacy study endpoint was absolute plaque reduction of the target lesions from baseline to immediately post procedure. The primary safety endpoint was the cumulative incidence of SAEs at 30 days.

Table of Contents

In the OASIS trial, 94.5% of lesions treated were behind or below the knee, an area where lesions have traditionally gone untreated until they require bypass surgery or amputation. Of the lesions treated in OASIS, 55% were comprised of calcified plaque, which presents a challenge to proper expansion and apposition of balloons and stents, and 48% were diffuse, or greater than 3 cm in length, which typically requires multiple balloon expansions or stent placements. Competing plaque removal devices are often ineffective with these difficult to treat lesions.

The average time of treatment in the OASIS trial was three minutes per lesion, which compares favorably to the treatment time required by other plaque removal devices. We believe physicians using other plaque removal devices require approximately ten to 20 minutes of treatment time to achieve desired results, although treatment times may vary depending upon the nature of the procedure, the condition of the patient and other factors. The following table is a summary of the OASIS trial results:

Item	FDA Target	OASIS Result
Absolute Plaque Reduction	55%	59.4%
SAEs at 30 days	8% mean, with an upper bound of 16%	4.8% mean, device-related; 9.7% mean, overall
TLR	20% or less	2.4%
Perforations	N/A	1 serious perforation
ABI at baseline	N/A	0.68 ± 0.2*
ABI at 30 days	N/A	0.9 ± 0.18*
ABI at 6 months	N/A	0.83 ± 0.23*

* Mean ± Standard Deviation

We submitted our OASIS data and received 510(k) clearance from the FDA for use of the Diamondback 360°, including the initial version of the control unit, with a hollow crown as a therapy for patients with PAD in August 2007. The FDA s labeling requirements reflected the inclusion criteria for the OASIS trial listed above. We received 510(k) clearances in October 2007 for the updated control unit used with the Diamondback 360° and in November 2007 for the Diamondback 360° with a solid crown. In May 2005, we received the CE mark, allowing for the commercial use of the Diamondback 360° within the European Union; however, our current plans are to focus sales in the United States.

OASIS Long-Term Study

A retrospective study evaluating the long-term results of 64 patients from the pivotal OASIS trial has been completed. Outcomes were analyzed out to a mean of 29 months and include limb salvage rate, target lesion revascularization rate (TLR) and ankle-brachial index (ABI). TLR, or reintervention in the originally treated lesion, was 13.6%. A 100% limb salvage rate was maintained. ABI scores remained significantly improved. This 29 month data of OASIS patients adds to our confidence in the safety and efficacy of the Diamondback 360°.

Post-Market Feasibility Studies

In May 2010, enrollment was completed in the COMPLIANCE 360° clinical trial, the first of two PAD post-market studies we initiated in calendar 2009. This prospective, randomized, multi-center study evaluates the clinical benefits of modifying plaque to change large vessel compliance above the knee with the Diamondback 360º. The study compares the performance of the Diamondback 360º, plus low-pressure balloon inflation, if desired, with that of

high-pressure balloon inflation alone. Fifty patients were enrolled at nine U.S. medical centers. The study is based on a six-month clinical endpoint; results will be reported subsequent to completion of six-month follow-up and data analysis.

In April 2010, enrollment was completed in the CALCIUM 360º study, a prospective, randomized, multi-center study, which compares the effectiveness of the Diamondback 360º to balloon dilation in treating heavily calcified lesions below the knee. Calcified plaque exists in about 75 percent of lesions below the knee. Fifty patients were enrolled at eight U.S. medical centers. Acute clinical results are being analyzed, and the first report of results

Table of Contents

occurred at the Transcatheter Cardiovascular Therapeutics Meeting in September 2010 in Washington, DC. This study will follow patients out to 12 months and results will be reported at six and 12 month intervals.

CONFIRM Post-Market Clinical Study Series

CSI is conducting the CONFIRM Post-Market Clinical Study Series, which will further evaluate acute, long-term, and economic parameters related to the use of the Diamondback Systems. The CONFIRM I Registry currently consists of two arms: CONFIRM DIAMONDBACK and CONFIRM PREDATOR.

Enrollment of 728 patients in the CONFIRM DIAMONDBACK Post-Market Registry was completed in March 2010. In this prospective registry, 1,138 lesions were treated by 84 investigators at 57 institutions with the Diamondback 360°. Patient characteristics were as follows: 81.6% were smokers, 60.0% were diabetic, and 89.7% had hypertension. Lesions treated were above the knee (46.5%), behind the knee (17.5%), and below the knee (36.0%). Lesions were long and calcified. Lesions were treated with the Diamondback 360° followed by low pressure balloon angioplasty, if desired. An average residual stenosis of 10.5% was achieved following treatment, which is consistent with that achieved in PAD I, PAD II, and OASIS. Bail-out stenting, or stenting required due to tears in the vessel wall, occurred in 2.2% of lesions, which is also consistent with the 2.5% reported in OASIS. This is lower than the 35 to 40% bail-out stent rate reported in the literature for patients treated with high pressure balloon angioplasty alone in this type of challenging patient population. Final results were reported at the Transcatheter Cardiovascular Therapeutics Meeting in September 2010 in Washington, DC.

Enrollment of up to 1,200 patients in the prospective CONFIRM PREDATOR Post-Market Registry commenced in August 2010. CONFIRM PREDATOR will evaluate clinical performance of the Predator 360°. Consecutive patients will be enrolled at up to 200 sites in the United States. Data on acute clinical performance and short-term economic parameters will be collected during this study. We anticipate enrollment will be complete by about March 31, 2010.

Data from CONFIRM I will be used to design future studies in the CONFIRM series to further evaluate long-term durability and economic parameters associated with use of the Diamondback Systems.

Sales and Marketing

We market and sell the Diamondback Systems through a direct sales force in the United States. While we sell directly to hospitals, we have targeted sales and marketing efforts to interventional cardiologists, vascular surgeons and interventional radiologists with experience using similar catheter-based procedures, such as angioplasty, stenting, and cutting or laser atherectomy. Physician referral programs and peer-to-peer education are other key elements of our sales strategy. Patient referrals come from general practitioners, podiatrists, nephrologists and endocrinologists.

We target our marketing efforts to practitioners through physician education, medical conferences, seminars, peer reviewed journals and marketing materials. Our sales and marketing program focuses on:

- educating physicians regarding the proper use and application of the Diamondback Systems;
- developing relationships with key opinion leaders; and
- facilitating regional referral marketing programs.

We are not marketing our products internationally and do not expect to do so in the near future; however, we will continue to evaluate international opportunities.

Research and Development

Our research and development efforts are focused in the development of products to penetrate our three key target markets: below-the-knee, above-the-knee and coronary vessels. Research and development expenses for fiscal 2010, fiscal 2009 and fiscal 2008 were $10.3 million, $14.7 million and $16.1 million, respectively.

Table of Contents

Manufacturing

We use internally-manufactured and externally-sourced components to manufacture the Diamondback Systems. Most of the externally-sourced components are available from multiple suppliers; however, a few key components, including the diamond grit coated crown, are single sourced. We assemble the shaft, crown and handle components on-site, and test, pack, seal and label the finished assembly before sending the packaged product to a contract sterilization facility. The sterilization facility sends samples to an independent laboratory to test for s